

Applicant: Girton, Timothy S.
Application No.: 09/704,494
Filing Date: November 2, 2000
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REMARKS

The application has been amended. Claim 12 has been amended to more clearly identify the inventive subject matter. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claim 12 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,764,560 to Mitchell (hereinafter "Mitchell"). More specifically, the Examiner states:

Mitchell discloses a method of producing a porous polytetrafluoroethylene tube useful in medical devices (col. 1, lines 60-61) comprising the steps of providing an IPN of siloxane and PTFE (col. 6, lines 42-53) and removing said siloxane from IPN (Table 5 shows amount of siloxane extracted), leaving a porous PTFE structure (Table 4 shows pore sizes formed).

The rejection is respectfully traversed. Applicant has amended claim 12 to indicate that the porous PTFE tube useful in medical devices has not been expanded or stretched.

Mitchell provides for an inter-penetrating polymeric network including a polymer structure with nodes and fibrils and a polysiloxane. Component (a) of Mitchell is listed as being any polymer capable of being stretched, drawn or expanded so as to obtain a microstructure

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characterized by nodes interconnected by very small fibrils. It is preferred to use PTFE. See summary of invention, column 3, lines 55-68. This embodiment may be used in medical devices.

In another embodiment of Mitchell however, it is contemplated that a first polymer network which is not stretched may be used with a second polymer network comprising polydiorganosiloxane. See column 6, lines 40-50. This embodiment is not used in medical devices. It is instead used in such applications as filters, pump packing, insulation for electrical cables, and as laminates useful in the manufacture of breathable wearing apparel. See column 6, lines 53-58.

It is therefore not contemplated to use a polymer network which is not stretched as a medical device. It is in fact taught in Mitchell that any IPN used in the capacity of medical devices must be stretched, or expanded PTFE. See column 1, lines 50-62, and column 3, lines 60-66. It would therefore not be an obvious alteration of Mitchell to use non-stretched PTFE matrices in this capacity. Mitchell in fact teaches away from this use, as it teaches embodiments where the polymeric matrices are not stretched, as not being capable for use in medical devices. See column 6, lines 49-60.

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Accordingly, withdrawal of the rejection under 35 U.S.C. §102 and reconsideration is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner has rejected claims 1-11 and 13-16 under 35 U.S.C. §103(a) as being unpatentable over WO 87/02996 to Mitchell ("Mitchell PCT Publication") in view of U.S. Patent No. 5,639,278 to Dereume et al. More specifically, the Examiner states:

Referring to claims 1-3, 7-8, 13, and 15-16, Mitchell discloses an endoprosthesis for replacing arteries and veins (page 2, lines 19-20), commonly known in the art as a graft. Mitchell discloses a method of forming the endoprosthesis by providing an IPN of siloxane and PTFE (page 13, lines 1-11, page 25, 26, 28) and extracting the siloxane (Table 5), leaving a porous polytetrafluoroethylene (Table 4). Mitchell does not disclose however using the endoprosthesis to cover a stent surface. Dereume teaches combining a radially expandable stent (22) in between two radially expandable grafts (23, 24), in order to provide increased support, enhanced tissue ingrowth, and means to cover an aneurysm in an artery or vein (column 2, line 64-column 3, line 4; column 3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent in between two grafts, with Mitchell's type of graft made of non-expanded porous PTFE, in order to provide an endoprosthesis that supports an artery or vein, covers an aneurysm, enhances tissue ingrowth, etc. enhancing the overall biocompatibility of the prosthesis.

Applicants respectfully traverse this rejection. The same rejection applies to claims 4-6, 9-11, and 14, and will be addressed below.

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As previously discussed, Mitchell provides for an inter-penetrating polymeric network including a polymer structure with nodes and fibrils and a polysiloxane. Also as previously discussed Mitchell provides two embodiments: (1) including a stretch polymeric network which can be used in medical devices, and (2) another with a non-stretched polymeric network which is used as filters, pump packing, insulation for electrical cables, and as laminates useful in the manufacture of breathable wearing apparel; i.e. not for use in medical devices.

It would therefore not be obvious to combine this non-stretched polymeric network in Mitchell with the medical device of Dereume as Mitchell teaches away from the use of a non-stretched polymeric network as a medical device.

The action has therefore failed to establish a *prima facie* case of obviousness because it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior document, or to combine documents to arrive at the claimed invention. The requisite motivation for relying upon the cited references and making the proposed combination must stem from some teaching, suggestion, or influence in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art, not from Applicants disclosure. *In re: Oetiker*, 977 F.2d 1443, 24 USPQ 2nd, 1443 (Fed. Cir. 1992).

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Because Mitchell teaches away from the use of a non-stretched inter-penetrating polymeric network as a medical device in the present case, not only would it not be obvious to combine it with the device found in Dereume, but one would be motivated away from this combination.

Withdrawal of the rejections based on 35 U.S.C. §103(a) is therefore respectfully requested and reconsideration is requested.

Should the Examiner have any questions regarding this response, or wish to discuss this matter in further detail, the Examiner is invited to contact Applicant's undersigned Attorney at the telephone number listed below.

Respectfully submitted,



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VERSION OF AMENDMENT WITH MARKING
SHOWING CHANGES MADE

IN THE CLAIMS:

12. (Amended) A method for producing a porous polytetrafluoroethylene tube useful in medical devices comprising the steps of:

providing an interpenetrating network of siloxane and polytetrafluoroethylene; and

removing said siloxane from said interpenetrating network leaving a porous polytetrafluoroethylene structure, wherein said porous polytetrafluoroethylene structure is not expanded PTFE.